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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/785,474      | 02/20/2001  | Rudolph Tanzi        | 0609.418002/JAG/JUK | 6844             |

26111 7590 10/18/2004

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EXAMINER

HAYES, ROBERT CLINTON

|          |              |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
|----------|--------------|

1647

DATE MAILED: 10/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

|  |   |                                     |  |
|--|---|-------------------------------------|--|
| <p align="center"><b>Office Action Summary</b></p> | <b>Application No.</b><br>09/785,474      | <b>Applicant(s)</b><br>TANZI ET AL. |  |
|  | <b>Examiner</b><br>Robert C. Hayes, Ph.D. | <b>Art Unit</b><br>1647             |  |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 July 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) 1-11 and 13-15 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 12 is/are allowed.
- 6) ☒ Claim(s) 16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-16 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)                                    | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Response to Amendment*

1. The amendment filed 7/28/04 has been entered.
2. Applicant's election without traverse of Group II (claim 12), as it relates to SEQ ID NO: 30 in Paper No. 2/20/04 was acknowledged in the previous Office action. However, because a search of SEQ ID NO: 30, as now illustrated, can reasonably encompass a search of SEQ ID NOs: 4, 28 & 32, the additional restriction requirement of Group II against these SEQ ID NOs is withdrawn.
3. The disclosure is objected to because of the following informalities: The current status of all nonprovisional parent applications referenced in the first sentence of the specification should be included (i.e., **now U.S. Patent No. \_\_\_\_**"). Appropriate correction is required.
4. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 because 37 CFR 1.821 (a)(2)(c-d) states that *each sequence disclosed must appear separately in the "Sequence listing" and in the text of the description* and claims *whenever described*. For example, the appropriate SEQ ID NOs must be recited when referring to Fig. 2A-2F and/or Fig. 1A-1F on the bottom of pages 5, 6 & 7 of the specification, as well as in *pp#* 0230 on page 65.

Note that failure to respond to both the requirements for sequence compliance and the restriction requirement below will be held as *nonresponsive*, and may result in *abandonment* of this application.

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5. The rejections of claim 12 under 35 U.S.C. 112, first paragraph, for lack of written description, and under 35 U.S.C. 102(e) as being anticipated by St. George-Hyslop et al. (U.S. Patent 6,210,919 B1) are withdrawn due to the amendment of the claim and Applicants' arguments.
6. Applicants' arguments filed 7/28/04 have been considered but were not found persuasive.
7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
8. Claim 12 is allowed.
9. Claim 16 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

As previously made of record for original claim 12, the specification describes only the "human" mutant PS1 polypeptides of SEQ ID NOs: 4, 28, 30 & 32, as well as how to generically produce epitope-bearing portions thereof (e.g., pgs. 7, 20 & 25-27 of the specification). In contrast, the genus of heterologous PS1 molecules that merely "comprise" fragments of polypeptides of SEQ ID NOs: 4, 28, 30 & 32 are not described; especially as it relates to the

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current claim encompassing other putative mammalian species, etc. of presenilin 1. In other words, no written description is provided in the specification for any different species of PS1 polypeptide molecules, except for the specifically described mutated human PS1 polypeptides of SEQ ID NOs: 4, 28, 30 & 32. Nor is any written description provided for any additional *functional* polypeptide sequences/allelic variants, etc. that “**comprise**” fragments that include the recited mutations within the polypeptides of SEQ ID NOs: 4, 28, 30 & 32. Thus, one skilled in the art cannot reasonably visualized any other functional heterologous amino acid sequence that comprise fragments of SEQ ID NOs: 4, 28, 30 & 32, except for the single disclosed human sequences of SEQ ID NOs: 4, 28, 30 & 32; thereby, not currently meeting the written description requirements of 35 U.S.C. 112, first paragraph.

Accordingly, *Fiddes v. Baird*, 30 USPQ2d 1481, 1483 (1993) held that claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class, in which the specification had provided an adequate description of only the bovine sequence. Similarly, only the single species of “human” mutated PS1 polypeptides of SEQ ID NOs: 4, 28, 30 & 32 have been described in the instant specification. Thus, Applicants are not in possession of the claimed genus at the time of filing the instant application, for the reasons made of record.

It is suggested that amending claim 16 to “an isolated mutant presenilin 1 (PS1) polypeptide [comprising] consisting of an epitope bearing amino acid fragment of at least 13 amino acids in length, wherein said amino acid fragment is selected from...”, should obviate this rejection. See MPEP 2163.

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10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (571) 272-0885. The examiner can normally be reached on Monday through Thursday, and alternate Fridays, from 8:30 AM to 5:30 PM.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (571) 272-0961. The fax phone number for this Group is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Robert C. Hayes, Ph.D.  
October 13, 2004

**ROBERT C. HAYES, PH.D.  
PATENT EXAMINER**



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